

Amendment and Response

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Serial No.: 09/446,323
Filed: 20 March 2000
For: DEVICE FOR TAKING AND EXAMINING SAMPLES

Remarks

The final Office Action dated 17 July 2002 has been received and reviewed. With claims 1, 13, and 19 having been amended and claims 22-23 having been added, the pending claims are claims 1-3, 7-8, and 10-23. Reconsideration and withdrawal of the rejections are respectfully requested in view of the accompanying RCE and the amendments and remarks provided herein.

Election/Restriction

Applicant notes the restriction requirement between group I (claims 1-20) and group II (claim 21). In the event the Examiner maintains the restriction requirement, rejoinder of the non-elected claims is respectfully requested upon notice of allowance of any of the elected product claims. Notably, the non-elected method claim include limitations of the elected product claims (see 1184 O.G. 86, citing In re Ochiai, 37 USPQ2d 1127 (Fed. Cir. 1995) and In re Brouwer, 37 USPQ2d 1663 (Fed. Cir. 1996)).

In the Drawings

The proposed drawing correction filed on 13 May 2002 has been approved. As corrected replacement drawings were filed along with the proposed drawing revisions, it is assumed that the drawings require no further action on Applicant's part. However, for the Examiner's convenience, a copy of the corrected drawings as previously filed on 13 May 2002 are included herewith.

In the Specification

The Examiner has reminded Applicant of the proper language and format for an abstract of the disclosure. However, no objection has been identified. As Applicant believes the abstract adheres to PTO requirements, no amendment to the abstract is included herein. If the Examiner

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objects to the abstract, it is respectfully requested that the next Official Communication identify the objectionable language and the basis for the objection.

The 35 U.S.C. § 112, Second Paragraph, Rejection

Claims 1-18 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, claims 1 and 13 were rejected due to the use of the phrase "can be." Applicant has amended claims 1 and 13 as provided herein. As a result, reconsideration and withdrawal of this rejection are respectfully requested.

The 35 U.S.C. §102 (b) Rejection

Claims 1-3, 8, 11-12, and 19-20 were rejected under 35 U.S.C. § 102 (b) as being anticipated by Bernstein (U.S. Patent No. 4,770,835).

Applicant respectfully traverses this rejection for at least the reasons enumerated in the previous response, which are herein incorporated by reference. For example, Applicant notes that the "testing means" (identified by the Office Action as reference number 18) is not displaceable within the "housing" (identified by the Office Action as reference number 13) as claimed. Moreover, the "cartridge" (identified by the Office Action as reference number 15) is also not displaceable within the housing as claimed in claim 1.

However, the Office Action of 17 July 2002 asserts that a "a process limitation describing the movement of the testing means and cartridge as being 'displaceable' has not received patentable weight, since process limitations do not receive patentable weight in a claim drawn to an apparatus. Additionally, [the] Examiner believes the testing means and cartridge of Bernstein are in fact 'displaceable' since Bernstein disclose[s] the placement and positioning of the vessels (e.g. cartridges) in the cylindrical tube (e.g. housing)." *Office Action*, page 5.

"A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the

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context in which it is used." M.P.E.P § 2173.05(g), emphasis added. As a result, the classification of a particular limitation in an apparatus claim as a process limitation is not important. Rather, what the limitation conveys to one of skill in the art must be examined. Thus, Applicant requests consideration of the "displaceable" recitation in each claim in which it occurs.

Moreover, Applicant submits that the word "displaceable" is a concise constructional feature of the claim that identifies design aspects, e.g., dimensions, of the respective elements so that relative displacement of the specific elements may occur.

Nonetheless, in order to move this case forward, Applicant has revised claims 1 and 19 to recite that the cartridge, during operation of the device, is displaceable within the housing. This amendment is intended to clarify the invention, i.e., the scope of each claim prior to amendment is intended to be the same as the scope of each claim after amendment.

Claim 12 already identifies that the testing means is operable to be displaced after having been introduced into the housing.

It is submitted that Bernstein fails to teach, or even suggest, displacement of its reagent compartment 15 during operation. As anticipation requires that each and every element of the claim be found in a single prior art document, an anticipation rejection of amended claims 1, 12 and 19 in view of Bernstein is improper. Claims 2-3, 8, 11, and 20 are also submitted to be novel both in view of their dependence and in view of the particular subject matter addressed therein. Reconsideration and withdrawal of the rejection are therefore requested.

The 35 U.S.C. § 103 Rejection

Claim 7 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Bernstein in view of Berger (U.S. Patent No. 4,269,237). Applicant traverses this rejection for at least the following reasons.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the documents themselves or in the

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knowledge generally available to one of ordinary skill in the art, to combine document teachings. Second, there must be a reasonable expectation of success. Finally, the prior art documents must teach or suggest all the claim limitations. *See* MPEP § 2142.

Applicant submits that, for the reasons discussed above with respect to the 35 U.S.C. § 102(b) rejection in view of Bernstein, each and every element of claim 1 (from which claim 7 depends) is not identified in the disclosure of Bernstein. For example, the cartridge, during operation of the device, is not displaceable within the housing as claimed. No teaching is identified within Berger that remedies this deficiency.

Moreover, Applicant submits that the Office Action has failed to provide any motivation to combine the teachings of Bernstein (directed to a device for self contained solid phase immunodiffusion assay) with those of Berger (directed to sump oil draining and collecting device for use with a motor vehicle). Without such a showing, *prima facie* obviousness is unsupported.

For at least these reasons, reconsideration and withdrawal of the rejection of claim 7 are requested.

Allowable Subject Matter and New Claims

Claims 13-18 were indicated as allowable if rewritten to overcome the 35 U.S.C. § 112, second paragraph, rejections and to include all the limitations of the base and intervening claims. Claim 13 has been amended as described above with respect to the remarks concerning the 35 U.S.C. § 112, second paragraph, rejection. Reconsideration and allowance of claims 13-18 are therefore respectfully requested.

Applicant further requests entry and consideration of new claims 22-23. These claims depend from claims 1 and 13, respectively, and find support in the specification as originally filed, see, e.g., page 8, paragraph 2.

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Summary

It is respectfully submitted that pending claims 1-3, 7-8, and 10-23 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
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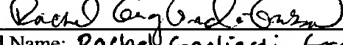
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The undersigned hereby certifies that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, **ATTN: BOX RCE**, Washington, D.C. 20231.

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APPENDIX A - CLAIM AMENDMENTS
INCLUDING NOTATIONS TO INDICATE CHANGES MADE
Serial No.: 09/446,323
Docket No.: 258.0004 0101

Amendments to the following are indicated by underlining what has been added and bracketing what has been deleted.

In the Claims

For convenience, all pending claims are shown below.

1. **(AMENDED)** A device for taking and examining samples, comprising a housing (50) in which a cartridge (30), a testing means (40) and a sample-taking means (10) are positioned, wherein the cartridge (30), during operation of the device, is displaceable within the housing (50) such that a sample introduced by means of the sample-taking means (10) is operable to form a sample mixture with a content of the cartridge (30), and wherein the testing means (40) is displaceable within the housing (50) [such that the testing means (40) can be brought in contact with the sample mixture for analyzing the sample mixture].
2. The device according to claim 1, wherein the sample-taking means (10) is operable to be introduced into an open end of the housing (50) and further wherein the sample-taking means (10) comprises a thread (18) which cooperates with a corresponding thread (53) in the housing (50).
3. The device according to claim 1, wherein a sample-facing end of the sample-taking means (10) comprises a sample chamber (20).
7. The device according to claim 1, wherein one end of the cartridge (30) comprises an opening (32) which can be closed by means of a ball (33).
8. The device according to claim 1, wherein the cartridge (30) has a bottom (34) operable to be perforated.

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10. The device according to claim 1, wherein the testing means has the shape of a cylinder and has an end that tapers in the form of a truncated cone (41), wherein a tip thereof has an opening (42).

11. The device according to claim 1, wherein the testing means (40) is operable to be brought in contact with the content of the cartridge (30) if the sample-taking means (10) is arranged in the housing.

12. A kit for preparing a ready-to-use device for taking and examining samples comprising :

- (a) a sample-taking means (10) for taking a sample;
- (b) a housing (50) with a cartridge (30) arranged therein; and
- (c) a testing means (40),

wherein the sample-taking means (10) and the testing means (40) are introducible into the housing (50) and the testing means (40) is operable to be displaced after having been introduced into the housing (50).

13. **(AMENDED)** A device for taking and examining samples, comprising a housing having positioned therein a cartridge, a testing means, and a sample-taking means, the sample-taking means comprising two half-tubes connected to each other, wherein the cartridge is displaceable within the housing such that a sample introduced by the sample-taking means is operable to form a sample mixture with a content of the cartridge, and wherein the testing means is displaceable within the housing [such that the testing means can be brought into contact with the sample mixture].

14. The device according to claim 13, wherein at least one of the two half-tubes comprises a first disk and a second disk defining a sample chamber.

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15. The device according to claim 14, wherein the first disk comprises a sieve and an indentation, and further wherein an edge of the first disk comprises a cone-shaped ring.
16. The device according to claim 15, wherein the cartridge is cylindrically shaped and comprises, on one end, a truncated cone engageable with the cone-shaped ring.
17. The device of claim 13, wherein the two half-tubes are connected by a joint, and wherein the joint is selected from the group consisting of a film hinge and an elastic web.
18. The device of claim 14, wherein the first disk is coupled to the sample-taking means with predetermined breaking points.
19. **(AMENDED)** A device for taking and examining samples, comprising:
a housing having a first end, a second end, and a passageway extending between;
a cartridge operable to be received in the first end of the housing, wherein the cartridge, during operation of the device, is displaceable within the passageway of the housing;
a sample-taking means operable to be at least partially received in the first end of the housing, wherein a sample introduced by the sample-taking means is operable to form a sample mixture with contents of the cartridge; and
a testing means operable to be received in the second end of the housing, wherein the testing means is displaceable within the passageway of the housing such that the testing means can be brought in contact with the sample mixture.
20. The device of claim 19, wherein the sample-taking means couples to the first end of the housing.

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21. A method for taking and examining samples, comprising:
collecting a sample in a sample-taking means;
coupling the sample-taking means to a first end of a housing, the housing having a cartridge located therein;
displacing the cartridge relative to the sample taking means;
combining the sample and contents of the cartridge to form a sample mixture;
providing a testing means at a second end of the housing; and
displacing the testing means relative to the housing, whereby the testing means contacts the sample mixture.

22. (NEW) The device according to claim 1, wherein the testing means (40) is displaceable within the housing (50) between a first position, in which the testing means (40) does not contact the sample mixture, and a second position in which the testing means (40) makes contact with the sample mixture.

23. (NEW) The device according to claim 13, wherein the testing means is displaceable within the housing between a first position, in which the testing means does not contact the sample mixture, and a second position, in which the testing means makes contact with the sample mixture.